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TITLE: The Effect of a Home-Based Walking Intervention on

Quality of Life, Body Composition, and Estrogen

Metabolism in Postmenopausal Breast Cancer Survivors

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Increased incidence of and survival from breast cancer have resulted in growth of the number of women who have survived this disease and are faced with the subsequent consequences of their diagnosis and treatment. Physical activity is a modifiable health behavior that has the potential to address both the emotional and physical needs of women with early stage breast cancer. However, for physical activity to be seen as a viable treatment option, and for a change in routine care to occur, its effectiveness must be determined. Accordingly, the objectives of this pilot study are to; 1) quantify the effect of a 12-week home-based walking intervention on quality of life, body composition, and estrogen metabolism in survivors of breast cancer, and 2) develop and test the feasibility of physical activity intervention materials for future studies in this population. We hypothesize that women randomized to the walking intervention will report higher levels of quality of life, experience less weight gain, and have more favorable estrogen metabolite profiles.

The recruitment of participants into this study has not yet been initiated due to challenges in institutional agreements regarding coverage of potential medical expenses incurred by women as a consequence of their participation in this research. During this period, our team has developed all necessary protocols for implementation of the study and maintained IRB clearance with all relevant IRB's.

14. SUBJECT TERMS breast cancer, exercis metabolism	se, quality of life, bo	dy weight, estrogen	15. NUMBER OF PAGES 12 16. PRICE CODE
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Introduction

Increased incidence of and survival from breast cancer have resulted in growth of the number of women who have survived this disease and are faced with the subsequent consequences. Diagnosis and treatment of breast cancer are associated with several adverse physical and psychosocial outcomes (e.g., weight gain, reduced physical activity levels, loss of lean body mass, depression, lowered self-esteem). Some of these adverse effects are attenuated after adjuvant treatment ends. However, psychological distress and weight gain may persist, resulting in reduced quality of life and increased risk of recurrence. Physical activity participation may attenuate the adverse effects outlined above and improve hormonal factors that influence breast cancer recurrence (1). Given these benefits, it is remarkable that physical activity programs have not been adapted for breast cancer survivors until very recently. In order for physical activity to be seen as a viable treatment option, and for a change in routine care to occur, its effectiveness must be determined. Accordingly, the objectives of this pilot study are to; 1) quantify the effect of a 12-week home-based walking intervention on quality of life, body composition, and estrogen metabolism in survivors of breast cancer, and 2) develop and test the feasibility of physical activity intervention materials for future studies in this population. We hypothesize that women randomized to the walking intervention will report higher levels of quality of life, experience less weight gain, and have more favorable estrogen metabolite profiles.

Body

DESIGN. Fifty postmenopausal women recently diagnosed with breast cancer will be recruited from the South Carolina Cancer Center (Columbia, SC). Thirty women will be randomized to a 12-week walking intervention and 20 women to a control group. The control group will be offered a walking program following the randomized experiment to allow them benefit from the intervention and improve compliance during the trial. All women will be screened for contraindications to the moderate-intensity walking program (i.e., anemia, immune suppression, extreme fatigue, bone pain, and symptoms of cardiovascular disease and orthopedic problems) and excluded as necessary. The intervention will occur after treatment is completed. Experimental groups will be balanced by stage of breast cancer and treatment type.

INTERVENTION. Participants randomized to the intervention will complete a 12-week home-based walking program using the Stanford model developed and refined by King and colleagues (1). Supervised home-based programs are preferred by most adults (5) and have been shown to be safe even in older ages and the obese. To maximize safety, participants will be instructed to gradually increase their walking duration and intensity. By the eighth week of the intervention, the goal will be to walk for 30-40 minutes, 5 times per week, at a moderate intensity level (i.e., 3-4 mph). Women in the intervention will have an initial in-person counseling session with a health educator that will emphasize physical activity safety (i.e., perceived exertion, warm-up, and cool-down). They also will receive 5 brief telephone calls by a health educator to monitor participant safety and enhance adherence during the 12-week intervention. Adherence will be monitored with self-report logs and pedometers. Dr. Sara Wilcox, a psychologist and Assistant Professor in Exercise Science at USC, will oversee the intervention.

OUTCOMES. Quality of life will be measured with the Medical Outcomes Study SF-36 that evaluates eight domains of life quality (e.g., physical, social, bodily pain, mental health). Changes in body mass and composition will be quantified with anthropometric measures and bioelectrical impedance. Estrogen metabolite levels will be measured among half of the overall sample (n=25) from spot urine samples in triplicate using the Estramet 2/16 kit (Immuna Care Corp, Bethlehem, PA). Women in the estrogen sub-study will only be included if they are overweight (i.e., body mass index > 25 kg/m²). The assay is a direct measure of 2-hydroxyestrone and 16alpha-hydroxyestrone. CYP1A2 activity, an enzyme regulating 2-hydroxyestrone formation, will be measured in urine. These markers of estrogen metabolism have been associated with breast cancer risk and physical activity levels. Changes in physical activity will be assessed by questionnaire and an accelerometer (2, 4). Outcomes will be measured at baseline, 6-, and 12-weeks. Availability of these data allow for examination of the effect of the intervention in returning women toward pre-diagnosis levels of physical and psychosocial health.

SUMMARY. This pilot study evaluates the effectiveness of a generalizable physical activity intervention for improving quality of life and two biologic factors associated with prognosis in postmenopausal breast cancer survivors. These data will provide the necessary quantitative estimates of outcome effect sizes that will be used for submission of a larger-scale proposal to rigorously test the hypotheses outlined above. This work has the potential to add an important new treatment option for the growing population of breast cancer survivors.

Key Research Accomplishments

Project Timeline

Letter of Award December 8, 2000 February 6, 2001 Protocol submitted to DOD IRB March 21, 2001 Notification of receipt DOD request for revisions May 1, 2001 Revised protocol submitted July 11, 2001 August 15, 2001 **Project Coordinator hired** HSRRB Review teleconference August 20, 2001 Review recommendations received August 27, 2001 Revised protocol submitted

HSRRB submits DOD IRB Approval internally

DOD indicates changes in institutional agreement needs to be addressed (insurance requirement)

Pending resolution of insurance

requirement

September 10, 2001 November 15, 2001

February 2002

September 2002

The study team has completed the entire advance planning for the project, including development of recruitment, data collection, intervention, and data management protocols. The project coordinator (Cheryl DerAnanian) has created all necessary questionnaires and the data management system. Connections with the clinical system to facilitate recruitment have also been established. The entire study infrastructure has been in place and ready to go since the Fall of 2001.

Continued delay will further jeopardize our ability to complete the work for which we were funded.

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Reportable Outcomes

With the assistance of developmental funding from the South Carolina Cancer Center (SCCC) for pilot work (completed in 1999-2000), we have recruited a number of women into a 12-week walking program. The primary objective of this data collection was to evaluate the effect of increasing physical activity on estrogen metabolism in overweight/obese women with early stage breast cancer. Complete data were collected for 13 women randomized to the 12-week intervention (n=8) and usual care (control) group (n=5).

In this preliminary project, 12 of 13 women completed the 12-week study (92%). The major results of this SCCC funded work set the stage for applying for the Concept Award; which enabled us to extend our recruitment to women of all body sizes (e.g., a more generalizable sample) and to strengthen our measurement protocol by including an objective assessment of physical activity.

Preliminary results from our work is reported in detail in abstract form and by reproduction of the posters presented by: (1) Dr. Wilcox at the Society for Behavioral Medicine's 2002 annual meeting (6), and (2) by Cheryl DerAnanian, M.S. at the 2002 Era of Hope meeting (3). Dr. Matthews (PI) was not able to attend the Era of Hope meeting due to the impending birth of his second child (due early October 2002).

Funds derived through the Concept Award mechanism funded both investigators in their presentation of this research at these meetings. Both of these posters were submitted with the hope of adding the newly collected Concept Award project to the analyses. This was not possible due to administrative delays.

Cheryl DerAnanian, M.S. is the project coordinator and lead interventionist for the Breast Cancer Walking Study. She is currently a doctoral candidate in the USC School of Public Health, Department of Health Promotion Education and Behavior. The Concept Award has been one of the research projects providing her graduate stipend to support her educational and research objectives at the University.

The continued administrative delays imposed on this research project have resulted in an unfortunately high number of lost opportunities (e.g., manuscript, abstracts, presentations, educational support, translation of pilot work to grant proposals [e.g., Concept -> IDEA Award], employment, and research opportunities).

Conclusions

Not yet available.

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APPENDICES

- A.1. Society for Behavioral Medicine (2001): Abstract and Poster
- A.2. Era of Hope (2002): Abstract and Poster

A.2. Society for Behavioral Medicine (2002): Abstract and Poster

ADHERENCE TO A HOME-BASED WALKING PROGRAM IN BREAST CANCER SURVIVORS: A PILOT STUDY

Sara Wilcox, Ph.D., Charles E. Matthews, Ph.D., and Amy Skiba, M.S. University of South Carolina

The diagnosis and treatment of breast cancer (BC) are associated with adverse physical and emotional outcomes. Physical activity (PA) has the potential to attenuate these adverse outcomes. This presentation describes the results of a 12-week pilot walking study developed for BC survivors. Participants (57 ± 13 years; 69% Caucasian; 31% African American) were randomized to an intervention (n=8) or a waist-list control group (n=5). Intervention participants received an in-person counseling visit and follow-up telephone-calls (Mean = 4.5 calls, 13 mins/call), based on Social Cognitive Theory, that focused on goal setting, reinforcement, social support, problem solving, and safety monitoring. They also kept a daily log of mins walked, perceived exertion, and steps/day (pedometer). Average mins/wk walked were 70, 78, and 83 at 1, 2, and 3 months. Adherence (sessions completed / sessions recommended) averaged 91%, 67%, and 57% across the 3 months. Steps/day were higher on walking (7023) than non-walking (4941) days (p<.01). Common barriers to walking were family issues, weather, work schedules, illness, and fatique. A self-report measure of PA (CHAMPS), indicated that MET-hrs/wk walked (all types of walking) increased from baseline to 6- and 12-weeks in intervention (2.9, 12.2, 16.6) but not control participants (5.8, 5.1, 7.2); Group x Time effect n.s.; effect size d = 1.51 and 1.97 at 6- and 12-weeks. This pilot study suggests that a home-based walking program is feasible for BC survivors, but strategies to further increase and sustain these changes over time are needed.

This study was supported by a grant from the South Carolina Cancer Center, #2000-21.

Sara Wilcox, Ph.D., Department of Exercise Science, NJA School of Public Health, University of South Carolina, Columbia, SC 29208.



Adherence to a Home-Based Walking Program in Breast Cancer Survivors A Pilot Study

Sara Wilcox, Ph.D., Charles E. Matthews, Ph.D., & Amy M. Skiba, M.S.

University of South Carolina, Norman J. Arnold School of Public Health, Columbia, SC.

Background

- cancer are associated with adverse physical Both the diagnosis and treatment of breast and emotional outcomes, including weight gain, fatigue, depression, and reduced physical activity
 - Most interventions that focus on improving quality of life in women with breast cancer
- potential to attenuate adverse physical and emotional outcomes in women with breast Physical activity interventions have the have been psychosocial in nature. cancer (1)

Purpose

The purpose of this presentation is to describe intervention for breast cancer survivors and to present the results of a pilot study testing this the development of a home-based walking intervention

Methods

Rating of Perceived Exertion during walking

minutes/day of walking

participants to assess:

steps/day (assessed using a Yamax®

sessions

Digiwalker pedometer)

adherence

Walking logs were completed by intervention

safety monitoring problem solving reinforcements social support

Measures

- Participants were 13 postmenopausal women who were breast cancer survivors
 - 8 were randomized to an intervention group
 - and 5 to a wait-list control group Mean age was 57 ± 13 years
- 69% were Caucasian, 31% were African American

programs developed at Stanford University (2) and was grounded in Social Cognitive Theory. The walking intervention was modeled after

intervention participants were family issues, weather,

work schedules, illness, and fatigue

The most common barriers to walking among

Results

Results, continued

Methods, continued

Data from walking logs (shown in Figures 1 & pedometer-measured steps/day increased over the three month period for women in the indicated that time spent walking and intervention group.

One individual, in-person counseling visit, which

Components of the intervention included:

discussion of program description and

instruction in safety issues

covered:

months. This decline was due to an increase in Adherence (actual / target walking sessions) averaged 91%, 67%, and 57% at 1, 2, and 3 target sessions over time rather than to an actual decrease in walking over time.

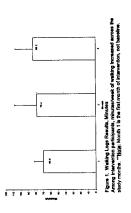
> instruction in using walking logs and pedometer 12 weeks of telephone-based behavioral counseling (Mean = 4.5 calls, 13 mins/call) focused on:

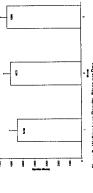
signing of a behavioral contract

expectations

self control (goal setting, self-monitoring, self

rewards)





Older Adults (3) was self-administered at baseline, 6-, and 12-weeks. MET hrs/wk spent in walking is

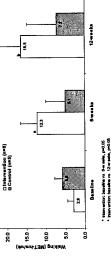
The CHAMPS Physical Activity Questionnaire for

Steps/day were also higher on walking (7023) than Figure 2. Walking Logs Results, Steps per Day.
Among intervention participants, stepsiday (sessered by pedomeken)
increased excess the study months. "NOSE Month 1 is the first month or intervention, not besein."

non-walking (4941) days, p < 0.01.

Results, continued

(MET-hrs/wk) increased at 6- and 12-weeks in intervention but Data from the CHAMPS questionnaire indicated that walking not control participants (see Figure 3).



eets among intervention but not control participants. The differences groups represent large effect sizes (d=1.51 and 1.97 at 6- and 12-weeks). Figure 3. CHAMPS Walking Results, MET-hra/w Walking increased at 6- and 12-weeks among init between intervention and control groups represe

Summary and Conclusions

- A home-based walking program is feasible for women who are breast cancer survivors.
 - Although significant increases in walking were seen at 6and 12-weeks, strategies to further increase and sustain these changes over time are needed.

References

Courneya KS, Friedenreich CM. Physical exercise and quality of life following cancer
diagnosis. A That also was the second of the

<u>Acknowledgements</u>

This study was supported by a grant from the South Carolina Cancer Center, #2000-21.

reported here.

A.2. Era of Hope (2002): Abstract and Poster

A HOME-BASED WALKING INTERVENTION AMONG BREAST CANCER SURVIVORS

C. E. Matthews, S. Wilcox, A. Skiba, S. Heiney, and C. Der Ananian N.J.A. School of Public Health, University of South Carolina, and the South Carolina Cancer Center

PURPOSE. This purpose of this study was to evaluate the feasibility of a home-based walking intervention among early-stage breast cancer (BC) survivors and to describe the impact of the intervention on quality of life (QOL) and physical activity (PA) levels.

METHODS. In this ongoing randomized pilot study we are evaluating the effect of a 12-week walking intervention (recruitment goal N=50). Participants were randomized to a home-based walking intervention adapted from the Stanford model (n=8), or a wait-list control group (n=5). Intervention participants received an in-person counseling visit and follow-up telephone-calls (mean = 4.5 calls, 13 min/call) that focused on goal setting, reinforcement, social support, problem solving, and safety monitoring. Daily walking logs and pedometers were employed as self-monitoring tools. Outcome measures were the SF-36 and CHAMPS PA questionnaires.

RESULTS. To date, 12 of 13 (92%) women have completed the study (age 57 \pm 13 years; 69% Caucasian; 31% African American). Baseline SF-36 indices for physical function, role-physical, and vitality were 20-40% below normative values for US women of similar age (55-64 yrs). No significant QOL changes were noted in response to the intervention in these preliminary analyses. Overall PA increased from baseline to 6- and 12-weeks in the intervention (2201, 3280, 3989 kcal/wk) but not control participants (1912, 1844, 2098 kcals/wk); Group x time p = 0.48. Walking increased from baseline to 6- and 12-weeks in the intervention (357, 1173, 1588 kcal/wk, p < 0.06 vs. baseline) but not control participants (358, 296, 466 kcals/wk, p > 0.82 vs. baseline); Group x time p = 0.19. Pedometer readings were higher on walking than non-walking days (7023 vs. 4941 steps/d, p < 0.01). Adherence to the walking intervention goals averaged 91%, 67%, and 57% across 3 months.

CONCLUSION. Preliminary results suggest that home-based walking programs are feasible for early-stage BC survivors and can increase PA levels. Accordingly, home-based walking programs have the potential to assist women in combating the adverse emotional and physical outcomes associated with the diagnosis and treatment of BC.

The U.S. Army Medical Research and Materiel Command under DAMD17-01-1-0628 and the South Carolina Cancer Center #2000-21 supported this work.



Abstract

PURPOSE. This purpose of this study was to evaluate the feasibility of a home-based walking intervention among early stage breast cancer (BC) survivors and to describe the impact of the intervention on quality of life (OCL) and physical activity

(PA) levels.
When this organic andomized plot study we are evaluating the effect of when the walling intervention (rectulinent goal N=50). Participants were a 12-way walling intervention solated from the Stanford

installation or a warkist control group (rev.) Intervention participate received an increase in country and a second sec

CONCLUSION: Preliminary results suggest that home based welking programs as a leasible for explicitly dated as Conclusion in increase 3 Project. Accordingly, home-based welking programs face the goodwale to assist women in contenting the experience of the properties to assist women in contenting the experience of the project of the pr

Background

Both the diagnosis and treatment of breast cancer are outcomes including weight gain, fatigue, depression associated with adverse physical and emotional and reduced physical activity

attenuate the adverse physical and emotional outcomes Physical activity interventions have the potential to in women with breast cancer (1).

Purpose

on quality of life (QOL) and physical activity (PA) levels. survivors and to describe the impact of the intervention To evaluate the feasibility of a home-based walking intervention among early-stage breast cancer (BC)

Wethods

were breast cancer survivors (Recruitment goal N=50) Participants were 13 post-menopausal women who

developed at Stanford University (2) and was grounded The walking intervention was modeled after programs In Social Cognitive Theory.

A Home-based Walking Intervention Among Breast Cancer Survivors

Charles E. Matthews, Ph.D., Cheryl Der Ananian, M.S., Sara Wilcox, Ph.D., Amy M. Skiba, M.S., And Sue Heiney, Ph.D.

Norman J. Arnold School of Public Health. University of South Carolina, and the South Carolina Cancer Center, Columbia, SC

Methods, continued

Components of the intervention included:

behavioral contract and instruction in using walking logs program description and expectations, signing of a covered: instruction in safety issues, discussion of One individual in-person counseling visit which and pedometer.

Mean = 4.5 calls, 13 mins/call) focused on: self control 12 weeks of telephone-based behavioral counseling reinforcements, social support, problem solving and (goal setting, self-monitoring, self rewards), safety monitoring.

of walking, rating of perceived exertion during walking the intervention participants to document minutes/day Walking logs were self-monitoring tools completed by and steps/day (Yamax® Digiwalker).

Measures

Adults (3) was self-administered at baseline, 6-, and 12-The CHAMPS Physical Activity Questionnaire for Older weeks. Kcal/wk spent in overall PA and walking are reported here. The SF-36 (4) was self-administered at baseline, 6- and 12-weeks. Indices for physical function, role physical and vitality are reported here.

Adherence was determined from the walking logs as actual walking sessions/ target walking sessions.

Basic characteristics of the participants are provided in To date, 92% of the women have completed the study. table 1.

Characteristic	Intervention (n=8)	Control (n=5)
Age (veers)	49.25 + 5.3	68.40 ± 13.1
Valor (lbs)	195,8 + 29.7	176.6 + 29.0
BMI (ka/m²)	33.4 + 3.61	30.7 + 3.67
African American	37%	20%
Caucasian	62%	80%
Time between disanosis and study entry		
(veers)	0.67 ± 0.13	0.89 + 0.10
Breast Cancer Diagnosis	Ì	
TMN Stage	Fii c	n = 2 (40%)
TMN Stage II	<u> </u>	n = 2 (40%)
TMN State III	===	
Not staged	T= c	n = 1 (20%)
Treatment Received*		
Chemotherapy	n=2	0=0
Radiation	- u	
Both Chemotherapy and Radiation	1 = 0	- = -
Hormone Therapy Only	0 !! C	- "

Results, continued

Baseline SF-36 indices for Physical Function (PF), participants were 20 - 40% below the normative values for U.S. women age 55-64 (Figure1). Role Physical (RP) and Vitality (VT) among

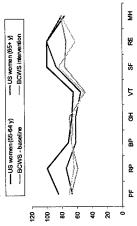


Figure 1. SF-36, Quality of Life Results

No significant changes in quality of life as assessed by overall physical activity energy expenditure (kcal/wk) increased at 6- and 12-weeks in intervention but not Data from the CHAMPS questionnaire indicated that the SF-36 were seen in these preliminary analyses

Dirtervention El Control control participants (see Figure 2).

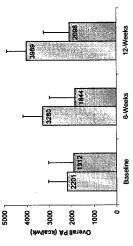


Figure 2. Champs Overall PA results, kcal/wk

Energy expenditure from walking (kcal/wk) as assessed by the CHAMPS questionnaire increased from baseline to 6- and 12- weeks among intervention participants but not control participants (See Figure 3).

Results, continued

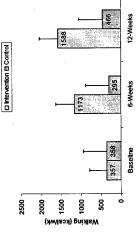


Figure 3. Walking Results, kcal/wk

Steps/day were higher on walking (7023) than nonwalking (4941) days, p < 0.01. Adherence (actual / target walking sessions) averaged 91%, 67%, and 57% at 1, 2, and 3 months. This decline was due to an increase in target sessions over time rather than to an actual decrease in walking over

Summary and Conclusions

- Preliminary results suggest that participation in a home-based walking program increases overall PA among early stage breast cancer survivors.
 - among early stage breast cancer survivors and is effective at producing short-term changes in A home-based walking program is feasible
- associated with the diagnosis and treatment of BC. potential to assist women in combating the adverse emotional and physical outcomes Home-based walking programs have the

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